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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/461,829 12/15/99 ENZERINK

R 265280-64723

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INDIANAPOLIS IN 46204

QM12/0717

EXAMINER

PELLEGRINO, B

ART UNIT

PAPER NUMBER

3738

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/461,829

Applicant(s)

ENZERINK ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/3/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 35-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 7-12, 14, 35-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McGuire (5562669). McGuire discloses that allografts comprising bone plugs and replacement ligaments sutured thereto are used to repair ligaments, col. 6, lines 32-42, 58-61. The allografts are preserved by freezing. It is well known in the art to package the graft in sterile packaging. McGuire also discloses that tendons such as the semitendinosus and gracilis are preferable because of their shelf-life, col. 6, lines 44-47. The graft can be a bundle of strands, col. 6, lines 60-61. With respect to claim 9, see col. 4, lines 20-26. McGuire additionally teaches that fixation devices are used in "kits" for ligament repair, col. 5, lines 17-22. Regarding claim 35, McGuire does disclose drilling holes in the bone plugs, but does not explicitly disclose having pre-attached sutures to the ligament. In the alternative, it would have been obvious to one of ordinary skill in the art to have pre-attached sutures to the ligament in order to save time in the surgery that would be required if the sutures were placed in the ligament while conducting the surgery.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669. in view of Prewett et al. '810. McGuire is explained supra. However, McGuire does not disclose lyophilization of allografts. Prewett et al. teach that graft tissue strength can be maintained by freezing or lyophilizing when packaging, col. 6, lines 31-

45. It would have been obvious to one of ordinary skill in the art to lyophilize an allograft as taught by Prewett et al. for the graft of McGuire in order to provide a durable replacement.

Claims 5, 6, 13, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669 in view of Schmieding '561. McGuire is explained supra. McGuire also discloses that allografts can be substituted for autografts and are frozen to preserve them until used, col. 6, lines 31-36. However, McGuire does not disclose the use of long strand sutures and various lengths of ligaments. Schmieding teaches that long strand sutures are placed on the graft to aid in placement in a patient, col. 5, lines 25-32. Schmieding also teaches to use various lengths for ligament repairs, col. 4, lines 56-66. It would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place.

Response to Arguments

Applicant's arguments with respect to claims 1, 12, 35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Heacox (RE 36132) teaches packaging and preserving tissue specimens.

Dumican et al. (4987665) discloses ligaments packaged in preservative and sterile packages.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

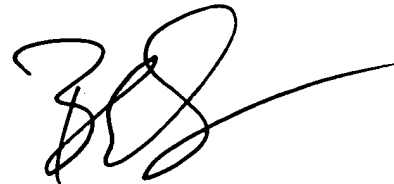
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino
July 10, 2001

Brian E. Pellegrino



Bruce Snow
Primary Examiner
TC 3700, AU 3738